

REMARKS

The Applicants thank the Examiner for the thorough consideration given the present application. Claims 11-14 are pending. Claims 6-10 were previously canceled. Claim 11 is independent and is amended herein. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

Acknowledgement of Information Disclosure Statement

The Examiner has acknowledged the Information Disclosure Statement filed on July 25, 2002, but has not acknowledged the Information Disclosure Statement filed on January 30, 2002 (see the Office Action Summary dated April 26, 2004). Clarification is requested in the next official communications.

Specification Changes

Section headings are added to the specification as suggested by the Examiner.

Rejection Under 35 U.S.C. §103(a)

Claims 1-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Anhauser et al. (U.S. 5,115,913) in view of WO 96/34633. This rejection is respectfully traversed.

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, independent claim 11 is amended herein to recite

a combination of method steps in a method of preventing pressure-sensitive adhesive from leaking out in cold-flow during prolonged storage of a pressure-sensitive adhesive substrate section which is sealed in a bag in order to be protected against loss of active substance, said substrate section comprising:

a backing layer; and

a matrix connected to said backing layer, the matrix either being comprised entirely of a pressure sensitive adhesive material or provided with a pressure-sensitive adhesive layer on an application surface thereof;

said method comprising the steps of:

providing a carrier layer on a pressure-sensitive application surface of the matrix, the carrier layer being divided by an incision, and

configuring the carrier layer with two carrier layer sections, the two carrier layer sections projecting at least partially beyond said matrix, and overlapping each other in a region where they are joined, said overlap being positioned on said pressure-sensitive adhesive substrate section.

Support for said overlap 4 being positioned on said pressure sensitive adhesive substrate section 6 can be seen in Fig. 1.

The Applicants respectfully submit that the combination of method steps set forth in independent claim 11, as amended herein, is not disclosed or made obvious by the prior art of record, including Anhauser et al. and WO '633.

The problem to be solved by the present invention was to prevent leakage of pressure-sensitive adhesive (due to cold flow) from pressure-sensitive adhesive substrate sections which are covered on their adhesive application surface with a carrier layer that is divided by an incision. This problem is solved, according to the present invention, by configuring this carrier layer with two overlapping sections, each section projecting at least partially beyond said matrix, and by positioning the overlap on the pressure-sensitive adhesive (PSA) substrate section.

According to the Examiner, (p. 5, first two lines), U.S. '913 (Anhauser et al.) teaches a method for prevention of cold flow by providing means to prevent migration of PSA by manipulating the carrier layer.

However, this interpretation does not appear to be correct. What US '913 does teach is how to prevent agglutination of the supporting layer with the packing after the PSA has already escaped from the outer margins of the substrate sections (col. 1, lines 44-53). The elevations (63) which serve as spacers between carrier layer and the surrounding packing prevent the agglutination of the supporting layer with the surrounding packing, due to the distance or empty space which is created by spacers.

In other words, US '913 does not teach how to prevent leakage of PSA during storage, but it rather teaches how to prevent agglutination if such leakage will occur during storage.

Therefore, the skilled person trying to reduce the problem of leakage caused by cold flow would may have considered this prior art document, as it does not disclose methods for preventing leakage but only methods for preventing agglutination after such leakage has already occurred.

Furthermore, the present invention aims at improving the storage stability of pressure-sensitive adhesive substrate sections having a PSA surface which is covered by a carrier layer which is divided by an incision to form a release aid (present specification, p. 1, first paragraph; present claim 11). U.S. '913 does not concern adhesive substrates which are covered on their adhesive surface with a two-part carrier layer (having an incision). Therefore, the skilled person striving to improve the storage stability of substrate sections which are covered by a two-part carrier layer, by preventing the leakage of PSA during storage, would not have considered this prior art document.

In conclusion, contrary to what was stated by the Examiner, US '913 does not teach a method for preventing cold flow, but a method for preventing the disadvantageous effects resulting from cold flow, that is agglutination. The "manipulation of the carrier layer" to which the Examiner alludes on p. 5, (lines 1-2) does not serve to prevent escape of PSA by cold flow, but to prevent the escaped PSA from agglutinating the carrier layer or substrate with the surrounding wall of the packing.

It might also be said that US '913 teaches away from the present invention, as it teaches that leakage caused by cold flow cannot be prevented as such, and that the skilled person should think about methods to prevent the PSA that has escaped from the substrate sections from adhering the substrate sections of the carrier layer to the inner wall of the packing. According to the teaching of US '913, this could be achieved by creating an empty space between the packing and the substrate contained therein. This teaching is fundamentally different from the teaching of the present invention, which aims at preventing leakage before agglutination can occur.

As regards WO '933, it should be noted that this document teaches nothing about the function of the peel strips and their potential role in preventing the escape of adhesive material caused by cold flow. The overlapping peel strips shown in Fig. 2 cover the surface of a drug reservoir which is not described as being adhesive, but as a "compress, swab, and the like" (p. 3, second paragraph). In the marginal zones of backing (2), the peel strips cover the adhesive surface (4) of the backing; these adhesive surfaces do not belong to the active substance-containing reservoir, and they do not form a pressure-sensitive adhesive layer on the application surface of the reservoir.

Therefore, contrary to what is required by claim 11, as presently amended, WO '933 does not teach to position the overlap of the carrier layer on a pressure-sensitive adhesive

substrate section. The overlap of the peel strips shown in Fig. 2 is positioned on top of a non-adhesive, active substance-containing compress or swab.

Furthermore, like US '913, WO '933 fails to address the problem of preventing the leakage of PSA due to cold flow during prolonged storage. Instead, WO '933 is concerned with preventing the migration (by diffusion) of active compound out of the compress-type reservoir into the backing layer to which this reservoir is attached. The phenomenon of leakage of active substance is not comparable to the phenomenon of leakage of PSA due to cold flow.

It was speculated on p. 6 (1st par.) of the Office Action that the skilled person would have replaced the carrier layer disclosed in US '913 by the carrier layer having two overlapping sections disclosed in WO '633, "motivated by the desire of WO '633 to keep the active agent in the reservoir at a constant level during prolonged storage."

Furthermore, in this part of the Office Action, the carrier layer of US '913 is described as having been "manipulated to protect against migration of PSA", which is apparently not correct. The carrier layer of US '913 has not been manipulated to prevent migration of PSA, but it rather has been manipulated to prevent agglutination (if migration (leakage) has already occurred, by providing the carrier layer with spacer means (claim 1).

As mentioned above, WO '633 does not refer to a substrate having an active substance-containing PSA layer which may suffer from cold flow, and this document does not teach

anything about the possible role of the peel strips in preventing loss of active substance or leakage of PSA (which is not mentioned anyway in WO '633).

Therefore, the skilled person desiring to "keep the active agent in the reservoir" could not have been motivated by WO '633 to replace the carrier layer of US '913 by the peel strips of WO '633, as the possible function of these strips with respect to preventing loss of active substance or preventing leakage of PSA caused by cold flow was not discussed in WO '633.

The only thing the skilled person could have learned from WO '633 with respect to preventing loss of active substance during storage is that when using a non-occlusive backing layer, it may be advantageous to interpose an occlusive foil between the active substance-containing reservoir and said backing layer, in order to prevent diffusion of active substances from the reservoir into and through said backing layer (WO '633, p. 2, last par.). However, this teaching has nothing to do with the problem underlying the present invention, and the solution proposed by the present invention, as defined in claim 11.

In conclusion, we take the position that the skilled person would have not have considered combining US '913 and WO '633 as suggested by the Examiner, and such combination would not have resulted in the invention as presently claimed.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

Application No. 09/980,211
Amendment dated July 26, 2004
Reply to Office Action of April 26, 2004

Docket No.: 3868-0103P
Art Unit: 1615
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CONCLUSION

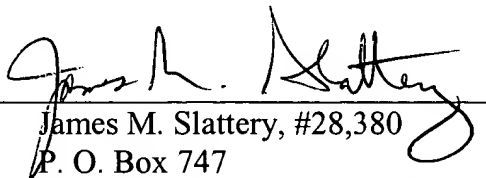
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 205-8000.

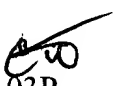
If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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